Page 1 of 3

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NUMBER

FILING OR 371 (c) DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NUMBER

10/824,661

04/15/2004

Michael Zasloff

036870-5045-14

009629 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 CONFIRMATION NO. 7684
FORMALITIES LETTER
OC000000013084940

Date Mailed: 06/28/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

08/31/2004 SZEWDIE1 00000067 500310

10824661

FILED UNDER 37 CFR 1.53(b)

01 FC:2001 02 FC:2202 03 FC:2203 385.00 DA

72.00 DA 145.00 DA

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.

 Applicant must submit \$ 770 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- A substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125, is required. The specification, claims, or abstract page(s) submitted is not acceptable and cannot be scanned or properly stored because:
 - The specification, claims or abstract page(s) 142-162 contain improper margins Each sheet must have a left margin of at least 2.5 cm (1") and top, bottom and right margins of at least 2.0 cm (3/4")
 - Papers must be legibly written either by a typewriter or mechanical printer in permanent ink or its equivalent in portrait orientation on flexible, strong, smooth, non-shiny, durable, and white paper. Application papers must be presented in a form having sufficient clarity and contrast between the paper and the writing thereon to permit the direct reproduction of readily legible copies in any number by use of photographic, electrostatic, photo-offset, and microfilming processes and electronic reproduction by use of digital imaging and optical character recognition. Pages 139,

142-162 are not in compliance with 37 CFR 1.52(a).

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121 are required. The drawings submitted are not acceptable because:
 - The drawings submitted to the Office are not electronically reproducible. Drawing sheets must be submitted on paper, which is flexible, strong, white, smooth, non-shiny, and durable (see 37 CFR 1.84(e)). See Figure(s) 9 Too Dark.

The following item(s) appear to have been **omitted** from the application:

- Figure(s) 17A, 17B described in the specification.
- I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$130.00 petition fee (37 CFR 1.17(h))) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if is determined that the item(s) was received by the USPTO.
- II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$130.00 petition fee (37 CFR 1.17(h)) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(e)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted items(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS <u>TWO MONTH</u> PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) or (b)**. In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (*i.e.*, the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

• Additional claim fees of \$434 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is \$1334 for a Large Entity

- \$770 Statutory basic filing fee.
- \$130 Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is \$434
 - \$144 for 8 total claims over 20.
 - \$290 for multiple dependent claim surcharge.

Replies should be mailed to:

Mail Stop Missing Parts

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

A copy of this notice <u>MUST</u> be returned with the reply.

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: Michael Zasloff et al. |) |
|---|--------------------------|
| Application No. 10/824,661 |) Art Unit: 1616 |
| Filed: April 15, 2004 |) Examiner: Not Assigned |
| For: Aminosterol Compounds Useful as |)) |
| Inhibitors of the Sodium/Proton Exchanger (NHE), Pharmaceutical Methods and |) |
| Compositions Employing Such Inhibitors, and Processes for Evaluating the NHE- |) |
| Inhibitory Efficacy of Compounds |) |

Mail Stop Missing Parts

U.S. Patent and Trademark Office 2011 South Clark Place Customer Window, Crystal Plaza Two, Lobby, Room 1B03 Arlington, VA 22202

RESPONSE TO NOTICE OF MISSING PARTS

- 1. This paper is filed in response to the Notice of Missing Parts of Nonprovisional Application dated June 28, 2004. A copy of the Notice of Missing Parts is enclosed.
- 2. Additional Papers Filed:
 - (i) Petition for Acceptance of Drawings
 - (ii) Copy of Figures 17A and 17B
 - (iii) Copy of U.S. Patent No. 5,847,172
 - (iv) Substitute Specification (163 pages)
 - (v) Submission of Replacement Drawings
 - (vi) 19 sheets of replacement drawings (Figures 1A-16)
 - (vii) Second Preliminary Amendment
- 3. Extension of Time: The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136(a) apply. Applicants do not believe a petition for extension of time is required. This request is being filed under the next business day rule on Monday, August 30, 2004 as the due date for responding fell on a Saturday (August 28, 2004). The Commissioner is hereby authorized to charge any additional fees which may be required, including fees due under 37 C.F.R. 1.16 and 1.17, or credit any overpayment to Deposit Account 50-0310.

4. <u>Fee Calculation</u> (37 C.F.R. § 1.16):

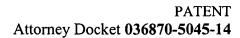
| CLAIMS FOR FEE CALCULATION | | | | | | | |
|---|-----------|-------|--------------------|-------|-------------|---------------------|--|
| | Remaining | | Previously Paid | Extra | Rate | Basic Fee: \$770.00 | |
| Total Claims | 28 | minus | 0 | 8 | \$18 each | 144.00 | |
| Independent Claims | 3 | minus | 0 | 0 | \$86 each | 0.00 | |
| First presentation of Multiple dependent claim \$290.00 | | | | | 290.00 | | |
| Sub-total = | | | | | = 1,204.00 | | |
| Reduction by ½ for filing by a small entity | | | | | - 602.00 | | |
| | | | . | | Total Fee = | \$602.00 | |

- 5. <u>Fee Payment</u>: The Commission is hereby authorized to charge \$797.00 to Deposit Account 50-0310 for payment of the application filing fee (\$385.00), the additional total claims fee (\$72.00), first presentation of multiple dependent claims fee (\$145.00), missing parts surcharge fee (\$65.00), and the petition fee (\$130.00).
- 6. Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, or credit any overpayment to Deposit Account 50-0310.

Dated: August 30, 2004 Morgan, Lewis & Bockius LLP Customer No. 09629 1111 Pennsylvania, N.W. Washington, D.C. 20004 202-739-3000 Respectfully submitted,
Morgan, Lewis & Bockius LLP

Gregory T. Lowen

Registration No. 46,882 Direct Dial: 202-739-5915





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: Michael Zasloff et al. |) |
|---|--------------------------|
| Application No. 10/824,661 |) Art Unit: 1616 |
| Filed: April 15, 2004 |) Examiner: Not Assigned |
| For: Aminosterol Compounds Useful as |) |
| Inhibitors of the Sodium/Proton Exchanger (NHE), Pharmaceutical Methods and |) |
| Compositions Employing Such Inhibitors, and Processes for Evaluating the NHE- |)) |
| Inhibitory Efficacy of Compounds |) |

SUBMISSION OF REPLACEMENT DRAWINGS

In response to the Notice to File Missing Parts of Nonprovisional dated June 28, 2004, Applicants submit nineteen (19) sheets of replacement drawings containing Figure 1A through Figure 16. It is respectfully requested that these drawings be approved and replace the drawings of Figure 1A through Figure 16 previously filed in the above-identified application.

If there are any fees due in connection with the filing of these drawings, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: August 30, 2004 Morgan, Lewis & Bockius LLP Customer No. 09629 1111 Pennsylvania Avenue, N.W. Washington, D.C. 20004 202-739-3000 Respectfully submitted

Morgan, Lewis & Bockius LLP

Gregory T. Howen Registration No. 46,882 Direct Dial: 202-739-5915